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मानक

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IS 5347-13 (1997): Requirements for orthopaedic implants, Part 13: Wrought high nitrogen stainless steel [MHD 2: Orthopaedic Instruments, Implants and Accessories]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक
अस्थि अन्तर्रोपणों की अपेक्षाएं
भाग 13 पिटवां उच्च नाइट्रोजन स्टेनलेस इस्पात

Indian Standard
**REQUIREMENTS FOR ORTHOPAEDIC
IMPLANTS**

PART 13 WROUGHT HIGH NITROGEN STAINLESS STEEL

ICS 11.040.40

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NATIONAL FOREWORD

This Indian Standard (Part 13) which is identical with ISO 5832-9:1992 'Implants for surgery — Metallic materials — Part 9 : Wrought high nitrogen stainless steel', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards, on the recommendation of the Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Standards on basic raw materials for orthopaedic implants are covered under various parts of IS 5347. A new raw material wrought high nitrogen stainless steel has been covered in this part of the standard. Since the material is used in the manufacturing of orthopaedic implants, the publication of this part of the standard was felt necessary. This will help the Indian implants manufacturers in getting the standard material.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 377-1 : 1989	IS 3711 : 1990 Wrought steel — Selection and preparation of samples and test pieces for mechanical test (<i>first revision</i>)	Technically Equivalent
ISO 404 : 1992	IS 8910 : 1978 General technical delivery requirements for steel products	do
ISO 437 : 1982	IS 228 (Part 4) : 1987 Methods for chemical analysis of steels : Part 4 Determination of total carbon by gravimetric method (for carbon greater than or equal to 0.1 percent) (<i>third revision</i>)	do
ISO 439 : 1994	IS 228 (Part 8) : 1989 Methods for chemical analysis of steels : Part 8 Determination of silicon by gravimetric method (for silicon greater than or equal to 0.1 percent) (<i>third revision</i>)	do
ISO 629 : 1982	IS 228 (Part 12) : 1988 Methods for chemical analysis of steels : Part 12 Determination of manganese by periodate spectrophotometric method in low and high alloy steels (for manganese 0.01 to 2.0 percent) (<i>third revision</i>)	do

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Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 13 WROUGHT HIGH NITROGEN STAINLESS STEEL

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, wrought stainless steel containing 0,25 % and 0,5 % nitrogen for use in the manufacture of surgical implants for which high levels of strength and corrosion resistance are required.

NOTES

1 The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this part of ISO 5832.

2 Requirements for other stainless steels for implants for surgery may be found in ISO 5832-1.

3 With regard to annealed wires, this part of ISO 5832 covers the mechanical properties of only those sizes for which data are available at present. Sizes other than those in table 4 may be requested by the purchaser, who should also state the ultimate tensile strength and elongation values required.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 377-1:1989, *Selection and preparation of samples and test pieces of wrought steels — Part 1: Samples and test pieces for mechanical test.*

ISO 404:1992, *Steel and steel products — General technical delivery requirements.*

ISO 437:1982, *Steel and cast iron — Determination of total carbon content — Combustion gravimetric method.*

ISO 439:1994, *Steel and iron — Determination of total silicon content — Gravimetric method.*

ISO 629:1982, *Steel and cast iron — Determination of manganese content — Spectrophotometric method.*

ISO 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size.*

ISO 671:1982, *Steel and cast iron — Determination of sulphur content — Combustion titrimetric method.*

ISO 3651-2:1976, *Austenitic stainless steels — Determination of resistance to intergranular corrosion — Part 2: Corrosion test in a sulphuric acid/copper sulphate medium in the presence of copper turnings (Monypenny Strauss test).*

ISO 4967:1979, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams.*

ISO 6892:1984, *Metallic materials — Tensile testing.*

ISO 10714:1992, *Steel and iron — Determination of phosphorus content — Phosphovanadomolybdate spectrophotometric method.*

3 Chemical composition

3.1 Test samples

The selection of samples for analysis shall be in accordance with the provisions of ISO 377-1.

3.2 Cast analysis

The cast analysis of the steel when determined as specified in clause 6 shall comply with the relevant chemical composition specified in table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (m/m)
Carbon	0,08 max.
Silicon	0,75 max.
Manganese	2 to 4,25
Nickel	9 to 11
Chromium	19,5 to 22
Molybdenum	2 to 3
Niobium	0,25 to 0,8
Sulfur	0,01 max.
Phosphorus	0,025 max.
Copper	0,25 max.
Nitrogen	0,25 to 0,5
Iron	Balance
Residuals	
each	0,1 max.
total	0,4 max.

4 Microstructure in fully annealed condition

4.1 Grain size

The austenitic grain size determined as specified in clause 7 shall be no coarser than grain size No. 4.

4.2 Absence of delta ferrite

The steel shall have a structure free from delta ferrite when examined as described in table 6.

4.3 Inclusion content

The non-metallic inclusion content of steel, determined at the billet stage, from a billet not exceeding 15 cm thickness, and specified in clause 7, shall not exceed the limits given in table 2.

NOTE 4 General practice is to use electroslag remelted steel to comply with these cleanliness requirements and to give other additional benefits.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content	
	Thin	Thick
A — Sulfides	1,5	1,5
B — Aluminates	2	1,5
C — Silicates	2	1,5
D — Oxides, globular	2,5	1,5

5 Corrosion resistance

The steel shall be capable of passing the intergranular Monypenny Strauss corrosion test specified in clause 7 when the test piece is heat-treated at 650 °C for 30 min and air-cooled prior to test.

6 Mechanical properties

The tensile properties of the steel in the form of bars, wires, and sheet and strip, determined as specified in clause 7, shall be in accordance with the requirements of table 3, table 4 and table 5 respectively.

Should any of the test pieces not meet the specified requirements or break outside the gauge limits, re-tests shall be carried out in accordance with the provisions of sub-clause 6.5 of ISO 404:1981.

7 Test methods

The test methods to be used in determining compliance with the requirements of this part of ISO 5832 shall be those given in table 6.

The selection and preparation of samples and test pieces for tensile testing shall be in accordance with the provisions of ISO 377-1.

Table 3 — Mechanical properties of bars

Condition	Diameter or thickness mm	Ultimate tensile strength	Yield strength 0,2 % offset	Elongation
		min. MPa	min. MPa	min. %
Annealed	Up to 80 mm	740	430	35

Table 4 — Mechanical properties of wires and rods

Condition	Diameter d mm	Ultimate tensile strength min. MPa	Elongation min. %
Annealed wire	$0,025 \leq d \leq 0,229$	See note 3 to Scope	
	$0,229 < d \leq 0,381$	1 340	25
	$0,381 < d \leq 0,508$	See note 3 to Scope	
	$0,508 < d \leq 0,635$	1 040	25
	$0,635 < d \leq 0,889$	1 030	25
	$0,889 < d$	1 030	25
	d	1 020	25
Cold-drawn rod ¹⁾	3	1 800	4
	3,5	1 740	4
	4	1 600	4
	4,5	1 460	4
	5	1 320	6
	5,5	1 200	8
	6	1 060	12
1) Original wire diameter 6,5 mm.			

Table 5 — Mechanical properties of sheet and strip

Condition	Ultimate tensile strength	Yield strength 0,2 % offset	Elongation
	min.	min.	min.
	MPa	MPa	%
Annealed	770	465	35

Table 6 — Test methods

Requirement	Relevant clause or sub-clause	Test method
Chemical composition Carbon Silicon Manganese Sulfur Phosphorus Other elements	3	ISO 437 ISO 439 ISO 629 ISO 671 ISO 10714 Recognized analytical procedure (ISO methods where these exist)
Grain size	4.1	ISO 643
Absence of delta ferrite	4.2	a) Metallographically prepared specimens in the annealed condition from longitudinal and transverse sections. b) Using recognized techniques, examine the specimen at × 100 magnification for the presence or absence of delta ferrite.
Inclusion content	4.3	ISO 4967, Method A, Plate II
Corrosion resistance	5	ISO 3651-2
Mechanical properties Ultimate tensile strength Yield strength Elongation	6	ISO 6892, as appropriate to the form of the steel

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<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 643 : 1983	IS 4748 : 1988 Method for estimating average grain size of metals (<i>first revision</i>)	Technically Equivalent
ISO 671 : 1982	IS 12308 (Part 2) : 1987 Method for chemical analysis of cast iron and pig iron : Part 2 Determination of sulphur by iodimetric titration after combustion (for sulphur 0.005 to 0.25 percent)	do
ISO 3651-2 : 1976	IS 10461 (Part 2) : 1994 Method for determination of resistance to intergranular corrosion of austenitic stainless steels : Part 2 Copper sulphate/sulphuric acid test (Monypenny straus test) (<i>first revision</i>)	do
ISO 4967 : 1979	IS 4163 : 1982 Method for determination of inclusion content in steel by macroscopic method (<i>first revision</i>)	do
ISO 6892 : 1984	IS 1608 : 1995 Mechanical testing of metals — Tensile testing (<i>second revision</i>)	do

This Indian Standard has been issued in 13 parts. Other parts of this standard are:

- Part 1 General requirements
- Part 2 Wrought stainless steel
- Part 3 Unalloyed titanium
- Part 4 Wrought titanium 6-aluminium 4-vanadium alloy
- Part 5 Cobalt-chromium-molybdenum casting alloy
- Part 6 Wrought cobalt-chromium-tungsten-nickel alloy
- Part 7 Wrought cobalt-nickel chromium-molybdenum alloy
- Part 8 Forgeable and cold-formed-cobalt-chromium-nickel-molybdenum-iron alloy
- Part 9 Ceramic materials based on alumina
- Part 10 Ultra-high molecular weight polyethylene, powder form
- Part 11 Ultra-high molecular weight polyethylene, moulded form
- Part 12 Wrought cobalt-nickel-chromium-molybdenum-iron alloy

Parts 14 and 15 of this standard are also under preparation and will be published shortly.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Additions'

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Amendments Issued Since Publication

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